

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jan Hall

App. No : 10/582,468

Filed : March 23, 2007

For : ARRANGEMENT OF AN IMPLANT
AND/OR A UNIT BELONGING TO
SAID IMPLANT, AND METHOD FOR
PRODUCTION OF THE IMPLANT
AND/OR UNIT

Examiner : Mai, Hao D

Art Unit : 3732

Conf No. : 4924

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April 27, 2010

(Date)

/Nathan S. Smith/

Nathan S. Smith, Reg. No. 53,615

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Jan Hall, declare that:

1. I am the named inventor of the above-referenced patent Application (the '468 Application).
2. I am currently an employee at Nobel Biocare, AB., which is the assignee of the '468 Application. As one of the inventors, it is my understanding that I will not receive any money from Nobel Biocare, AB upon issuance of the '468 Application as a patent.
3. I earned a Master of Science in Engineering Physics in 1981 from Chalmers University of Technology in Sweden. I also undertook doctoral studies during the years 1983-1990. I served in a post-doctoral position from 1990-1993 at the Technical University of Denmark. I was employed as a Biomaterials Research Engineer from 1993-2001 at Nobel Biocare AB. During the years 2001-

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2007, I was employed as a Senior Scientist at Nobel Bicoare AB. In 2007, I was promoted to Chief Scientist at Nobel Biocare AB.

4. I have spent considerable time with research related to titanium oxide surfaces. I am also the inventor of the well-known titanium oxide surface TiUnite.

5. I have reviewed the prosecution history of the ‘468 Application including the most recent Office Action dated October 27, 2009 and the article by Sul et al. (article: Resonance frequency and removal torque analysis of implants with turned and anodized surface oxides).

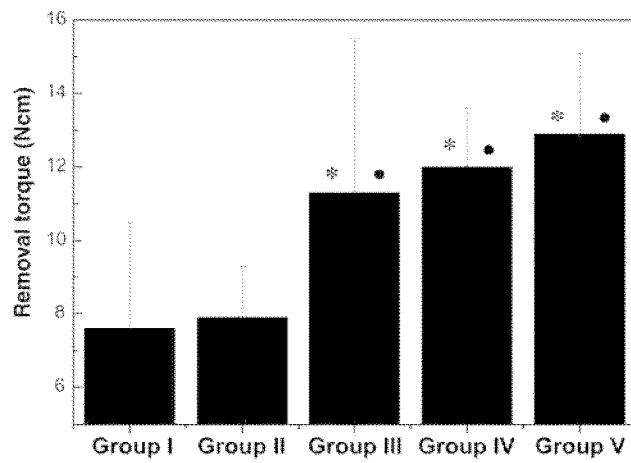
6. The ‘468 Application claims and describes a dental component and method by which dental component can extend at least partially in a hole formed in the jaw bone and through the soft tissue belonging to the jaw bone. An embodiment of the dental component can comprise, *inter alia*, “one or more titanium dioxide layers applied on at least one outer surface of the dental component, wherein between about 70-100% of each layer comprises crystalline titanium dioxide in the anatase phase.”

7. The purpose of treatment with dental implants is to provide the patient with teeth for function and aesthetics. Every patient desires that an implant be successfully integrated into the jawbone, have a reasonable cost, and provide an aesthetically pleasing integration which does not degenerate over time. In recent years, the need for providing even better dental components that can be implanted and integrated in bone in a short period of time has evolved.

8. As described in the ‘468 Application, there is a need for even better implants and units and for methods for production of implants and units. Thus, for example, it is important that bone growth can be improved and accelerated in connection with implants. There is an evident need for short integration times, and it is more difficult for patients and dental personnel to accept long and protracted treatment periods. It is also important to achieve good esthetic long term results. To that end, the ‘468 Application discusses the use of titanium dioxide to form an outer surface on an implant. *See Present Application, ¶¶ [0005]-[0010].* In particular, the ‘468 Application discloses an oxidation method by which titanium oxide is crystallized largely or

completely in the anatase phase, such that a proportion of 70% to 100% of an outer layer of the implant. *See Present Application, ¶¶ [0005]-[0006].* The implant can comprise one or more such layers in a thickness range of between about 0.05-10 micrometers, and preferably between about 0.5-10 micrometers.

9. The Sul reference discusses an experimental study that was performed to investigate whether oxide properties of titanium implants influence bone tissue responses in an experimental rabbit model. *See Sul, Abstract.* Sul investigated “a variety of surface oxide properties, such as oxide thickness, pore configuration, crystal structure, chemical composition, and surface roughness.” *See id.* at 253, col. 3. The study used implant samples divided into five groups according to the anodic forming voltage used to form the titanium oxide surface layer on the implant samples. *See id.* at 254, col. 1. The titanium oxide of the implant samples of Groups I-III are characterized as being in the amorphous phase, i.e., lacking any crystallinity, while the samples of Groups IV-V seem to be characterized as having some crystalline phase or a mixture of crystalline phases. *See id.* at 254, col. 2.



Number of implants	Group I	Group II	Group III	Group I	Group
Mean	7.5	7.9	11.3	12	12.9
SD	2.9	1.4	4.2	1.6	2.2
P-value (I)	.	0.999	0.023	0.006	0.001
P-value (II)	.	.	0.044	0.013	0.002

Fig. 1. Mean values of the peak removal torque measurements (Nm) after six weeks of healing time, demonstrating statistically significant differences between Groups I and III, Groups I and IV, Groups I and V, Groups II and III, Groups II and IV, and Groups II and V. *P*-value (I) indicates the significance level in the comparisons of Groups II-V with Group I, while *P*-value (II) indicates the significance level in comparisons of Groups III-V with Group II. **P*<0.05 in comparisons of Groups II-V with Group I. •*P*<0.05 in comparisons of Groups III-V with Group II.

10. However, as one of skill in the art, I understand Sul to be inconsistent regarding the description of specific crystalline phases in the overall disclosure, the abstract (lines 10-11), and Table 1. In the overall disclosure of Sul, I believe that Sul teaches that Group IV used a combination of amorphous and anatase titanium dioxide and that Group V comprises a combination of anatase and rutile phase. In Table 1, the crystal structure of Group IV is referred to as amorphous. In the Sul abstract, line 10, it is stated that, "the crystal structures of the titanium oxide were amorphous, anatase and a mixture of anatase and rutile." Thus, the overall impression from the Sul abstract is that a pure anatase structure existed, but such a structure is not present either in the manuscript or in Table 1.

Table 1. Summary of oxide growth parameters and surface characteristics of the five different types of c.p. titanium implants

Oxide characteristics	Turned implants Group I	Group II	Anodised implants Group III	Group IV	Group V
Anodic forming voltage ¹	-	100 V	200 V	280 V	380 V
Oxide growth constant	-	2.03 nm/V	3.04 nm/V	2.38 nm/V	2.63 nm/V
Anodic oxide forming rate	-	16.7 nm/s	15.2 nm/s	8.9 nm/s	7.7 nm/s
Oxide thickness ²	17 – 6 nm	202 – 53 nm	608 – 127 nm	805 – 112 nm	998 – 199 nm
Morphology ³	Turned grooves >10 µm Occasional pit and protusion	Barrier oxide film superimposed to the turned grooves > 10 µm negligible	Porous structure	Porous structure	Porous structure
Pore size distribution ⁴	-	-	1.27 µm ² by area and ≈ 8 µm by length	1.53 µm ² by area and ≈ 8 µm by length	2.10 µm ² by area and ≈ 8 µm by length
Porosity	-	Negligible	12.70%	20.40%	18.70%
Crystallinity ⁵	Amorphous titanium oxide primarily TiO ₂ and traces: C, Ca, Na, Si	Amorphous titanium oxide Primarily TiO ₂ and traces: C, Ca, Na, Si	Amorphous phase Primarily TiO ₂ and traces: C, Ca, Na, Si	Amorphous phase Primarily TiO ₂ and traces: C, Ca, Na, Si	Anatase rutile phase Primarily TiO ₂ and traces: C, Ca, Na, Si
Roughness (Sa) ⁶	0.83 – 0.32 µm	0.96 – 0.34 µm	1.03 – 0.33 µm	1.02 – 0.27 µm	0.97 – 0.30 µm

¹Voltages were continuously recorded at intervals of 0.5s by an IBM computer that was interfaced with the dc power supply

²Measured by continuous sputter etching with 4KeV Ar ion in Auger Electron Microscopy (AES) at four different locations on each implant: one thread top, one thread valley, one thread flank and in the head of the screw implant

³Characterised by Scanning Electron Microscopy (SEM)

⁴Analysed by Image analysis system (Bildanalyssystem AB) on negatives of the SEM pictures

⁵Measured with thin-film X-ray diffractometry (TF-XRD) and Raman spectroscopy

⁶Performed with X-ray Photoelectron Spectroscopy (XPS) with both monochromatic and non-monochromatic X-ray sources

⁷Measured with confocal laser scanning profilometer (TopScan3D[®]) with 245 × 245 µm² of measuring area, in each of the three thread tops, three thread valleys and three thread flanks, with a total of 27 measurements for each group

11. Based on the analysis and teachings of Sul, as one of skill in the art, I believe that Sul teaches that it is advantageous for the increase of renewal torque when the titanium oxide layer includes the properties of any one of Groups III-V. *See id.* at Fig. 3.

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12. The Office Action states that, a person of skill in the art would “make the implant of Group IV being at least 70%-100% of anatase phase in order to make experimental comparisons at least between Group IV (anatase) and Group V (mixture of anatase and rutile).” Office Action, page 3.

13. Contrary to the assertions of the Office Action, I believe that Sul actually teaches away from increasing the proportion of the anatase phase. Instead, as a person of skill in the art, I believe the experimental data presented by Sul indicates that the measured removal torque is silent as towards possible benefits of the crystal phases of the oxide layer on the implant. Studying Table 3 above we note that the difference in removal torque is significant only when the Group of I and II are compared with the Group of III, IV, and V. If the content of anatase were contributing to the increased removal torque, one would expect that the difference would be significant between Group I-IV and Group V and not between Group I-II and Group III-V. Furthermore, Sul does not give any hint with regard to the proportions or ranges of phases of titanium dioxide.

14. Sul simply does not support the idea that a person of skill in the art would experiment by creating implants that have 70% to 100% anatase phase titanium dioxide. The Sul article mainly aims to categorize different properties, such as oxide thickness, pore configuration, crystal structure, chemical composition, and surface roughness without giving any certain priority. In the article, it is concluded that oxide properties of titanium implants, which include oxide thickness, micropore configurations and crystal structures, greatly influence the bone tissue response in the evaluation of removal torque values. However, it is not fully understood whether these oxide properties influence the bone tissue response separately or synergistically. *See Sul, Last Passage of Abstract.*

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15. The claimed invention also addresses a long met need in the industry. As discussed above, patients generally need an implant that can integrate and provide sufficient stability within the shortest amount of time possible. This is especially useful in situations where the patient has sub-optimal bone density/volume. The claimed invention addresses these problems by providing an unexpectedly effective outer surface layer that provides faster osseointegration and better implant stability than outer surface layers of other implants. Moreover, I know of no publications or product beside my own patent Application that addresses this problem as described in my patent Application.

16. All statements made herein of my own knowledge are true. All statements made on information and belief is believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the Application or any patent issuing therefrom.

Jan Hall
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APRIL 21, 2010
Date

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